DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

November 20, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 01-07

Fernando Lamas, M.D.
Jefferson General Hospital
834 Sheridan Street
Port Townsend, Washington 98368

Re: Inspection #1621070006

WARNING LETTER

Dear Dr. Lamas:

We are writing to you because on November 2, 2000, a representative of the State of Washington, Bill Van Pelt, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 finding at your facility:

Processor QC records were missing 5 consecutive days for processor 0000000001, [redacted] Main room.

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as level 1 because it indicates a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to: placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially

comply with, the Standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

In addition, your response should address the four level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These level 2 findings are:

1. Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit 2, [redacted] room Mammo Room;

2. The interpreting physician, [redacted] did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography. [redacted] of your facility sent a fax to Mr. Van Pelt on November 6, 2000, which contained an attestation from [redacted] on this issue of initial training and experience (see also #3 below). This documentation, however, did not satisfy the MQSA requirements and Mr. Van Pelt notified her of this on the same day.

3. The interpreting physician, [redacted] did not meet the requirement of having initial experience in mammography (read or interpreted 240 patient examinations in a 6 month period).

4. Processor QC records were missing 5 out of 21 days of operation in month 10/2000. Processor QC records missing 24%, for processor 0000000001, [redacted], room Main.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).*

Please submit your response to U.S. Food & Drug Administration, Attention: Thomas S. Piekarski, Compliance Officer, 22201 23rd Drive, SE, Bothell, Washington 98021-4421.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law.

You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

Sincerely,

Charles M. Breen
District Director

*This note is not applicable for letters that also address patient notification.

cc: Priscilla F. Butler, M.S.
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American College of Radiology
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Bill Van Pelt
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